REMARKS

Reconsideration of the above-identified patent application in view of the following remarks is respectfully requested.

Claims 1-20, 29, 30, 32, 35-38 and 41-49 are in this application. Claims 10-20, 32 and 46 have been withdrawn. Claims 1-9, 29, 30, 35-38, 41-45 and 47-49 have been rejected under 35 U.S.C. 112. Claims 1-9, 35-37, 43-45 and 47-49 have been rejected under 35 U.S.C. 103(a). Claim 47 has been canceled. Claims 1-7, 9, 29, 30, 35-38, 41-45, 48 and 49 have been amended.

The claims before the Examiner are directed towards a stent assembly comprising an expandable stent with a cylindrical jacket, the jacket of heterologous tissue that is less than 0.45 mm thick and is relatively impervious so as to prevent tissue buildup. In such a way, a stent assembly supports patency of a lumen and simultaneously resurfaces a vessel in which it is deployed with a complete strong, smooth barrier. The fact that jacket is substantially a very thin graft is advantageous as the caliber of the lumen is only slightly reduced, substantially preventing the formation of a bottleneck to flow in the lumen. Further, the fact that the graft is relatively impervious prevents uncontrolled cell growth, especially of smooth muscle cells, that often leads to occlusion of vessels wherein permeable grafts are placed.

The claims before the Examiner are also directed towards an expandable jacketed stent comprising a metallic tubular member configured to expand from a first circumference to a second circumference and a cylindrical jacket formed of thinned heterologous tissue less than 0.45 mm thick, which is relatively impervious so as to prevent tissue buildup and migration of smooth muscle cells and which encircles the outer surface of the tubular member in a wrapped configuration where the cylindrical jacket is configured to unwrap as the tubular member expands from the first circumference to the second circumference.

35 U.S.C. 112, First Paragraph Rejections

The Examiner has rejected claims 1 and 29, and consequently all claims dependent thereform, under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. Specifically, the Examiner posits that the phrases " *impervious so as to prevent tissue growth*" in claim 1 and "*impervious to tissue in-growth*" in claim 29 constitute new matter. Applicant respectfully traverses this position. Despite this and in order to expedite prosecution, Applicant has chosen to amend claim 1 and 29 in accordance with suggestion of the Examiner and has replaced these two phrases with the phrase "*relatively impervious so as to prevent tissue buildup and migration of smooth muscle cells*" from page 9 ll. 4-6.

35 U.S.C. 103(a) Rejections – 6,117,166 (Winston *et al.*)

The Examiner has rejected claims 1, 2, 9, 37 and 43-45 as being obvious in light of Winston *et al.* Applicant respectfully traverses this rejection.

Winston *et al.* provide a device to simultaneously preserve patency and to resurface the internal walls of damaged blood vessels. The strategy chosen by Wilson *et al.* is that of re-growing a healthy endothelial layer on damaged inner surface of a blood vessel by bringing endothelial cells in proximity to the inner surface. The endothelial cells migrate to and grow over the damaged inner surface. To this end, Winston *et al.* teach a device having two main components, a stent for supporting the walls of an artery and a meshed graft that is secured to the endovascular stent. For use, the stent with the graft is deployed within a blood vessel in such a way that the graft is pressed against a part of the blood vessel that is damaged. The graft is characterized in being a section of arterial or venous tissue including only the intimal

layer of endothelial cells (c.5 ll. 10-14). Layers of endothelial cells from arterial or venous tissue are characterized in being permeable, suitable for cell growth thereupon and therethrough. When in place, the graft begins to disintegrate as endothelial cells migrate to and grow upon the damaged blood vessels wall, ultimately forming a new healthy endothelial layer. An advantage of such a graft is that its use avoids the use of pharmaceutical agents (c.2 ll. 28-30). Wilson *et al.* further teach perforating a graft using a tissue mesher (c.2. 1.15) as meshed grafts have increased expanding capacity, more flexible coverage and enhanced endothelial cell mobility (c.2 ll. 2-4, c.3 ll.50-59) allowing quick migration of healthy endothelial cells from the graft to the surrounding tissue.

Winston *et al.* do not teach or even hint all of the limitations of a stent assembly described in claim 1. Specifically, the graft of claim 1 is "*...relatively impervious so as to prevent tissue buildup and migration of smooth muscle cells...*" whereas the graft of Winston *et al.* is substantially a layer of endothelial cells (c.5 ll. 13-16) that is necessarily permeable.

As discussed hereinabove, graft permeability is a critical aspect of Winston *et al.*'s invention, allowing migration of endothelial cells (*inter alia*, c.2 ll.3-4, c.3 ll.34-36, c.4 ll.29-31, c.4 ll.49-50, c.4 ll.62-66) from the graft to the surface of the blood vessel. In contrast, the relative imperviousness of a graft of claim 1 is a critical aspect of the instant invention. In fact the device of Winston *et al.* and the stent assembly of the instant application are configured for related but entirely different tasks in the field of surgery.

It is thus clear that the differences between the device taught by Winston *et al.* and a device of the present invention are not such that the device of the present invention would be obvious to one of ordinary skill in the art. On the contrary, as described above, Wilson *et al.* teach an entirely different solution for a different problem and as such teach away from the device of the present invention. One of ordinary skill in the art studying Wilson *et al.* would

be motivated to seek improvements to increase endothelial cell migration from a graft, for example by increasing graft porosity. Such a person would have no motivation whatsoever to use any tissue as a graft except for endothelial tissue, as another tissue would defeat the strategy of Wilson *et al.*, that of restoring an endothelial layer to a damaged blood vessel. Further, such a person would have no motivation whatsoever to seek a relatively impervious graft as cell migration from such a graft would slow or entirely stop, totally defeating the strategy of Wilson *et al.*

35 U.S.C. 103(a) Rejections – WO 97/24081 (Love) in view of 6,117,166 (Winston *et al.*)

The Examiner has rejected claims 1-4, 6-9, 36, 37, 43-45 and 47-49 under 35 U.S.C. 103(a) as being unpatentable over PCT patent application PCT/US96/20868 published as WO 97/24081 (Love) in view of U.S. Patent 6,117,166 (Winston *et al.*). Applicant respectfully traverses this rejection.

Love teaches a vascular implant to support and seal a damaged blood vessel. The vascular implant includes a tissue graft that is rolled about the outside of a separate support frame so that adjacent longitudinal edges are overlapped (p.4 ll. 25-29). The tissue graft substantially consists of a harvested tissue that is cut to size and, in some cases, treated with a cross-linking agent or other stabilizing agent. The overlapping ends and use of relatively thick tissue for fashioning the graft causes a drastic reduction in the caliber of a lumen when the implant is deployed. The reduction of the caliber of the lumen leads to the formation of a bottleneck that leads to turbulent flow and eventual occlusion of the lumen. In embodiments of Love the support frame is a stent, but in no case is the use of an expandable stent proposed.

Amongst the features of claim 1 that Love does not teach are thinned tissue, a graft that is less than 0.45 mm thick and use of an expandable stent with a relatively impervious graft.

The Examiner alleges that the mere setting forth of a thickness is not considered sufficient to support patentability and would have been obvious to one of ordinary skill. Further, the Examiner states that there is no criticality set forth for the less than 0.45 mm thickness of a graft of the present invention. Applicant respectfully disagrees. One skilled in the art is well aware that the thickness of an arterial graft is of critical importance and this fact does not need to be recited. The thinner the graft, the less the blood flow through a treated blood vessel is restricted. It is clear that a thin graft is preferred to reduce the chance that a consequent bottleneck lead to arterial occlusion. There is a well-known need for thin grafts and providing a graft that is thinner than what is known in the art is considered to be a significant advancement of the field.

As discussed hereinabove, Winston *et al.* provide a thin, permeable and perforated graft for resurfacing blood vessels where the structural integrity of the treated blood vessel is not compromised and there is a need only to regenerate the inner surface of the vessel with endothelial cells. There is no requirement that a graft useful in implementing such an approach be mechanically strong. Further, as such a graft is configured to disintegrate as the individual endothelial cells migrate, such a graft is easily configured to be deployed using an expandable stent: such a graft can suffer tearing or deformation during expansion as there is no need for the graft to maintain any structural integrity.

In contrast, the device of the present invention and the device of Love are configured to resurface a blood vessel that may be scarred, physically damaged, have thin walls, weak walls or protrusions with a complete, strong and smooth barrier. Providing a graft that is

relatively impervious prevents uncontrolled cell growth that often leads to occlusion of vessels resurfaced with permeable grafts.

As discussed above, three features of claim 1 that Love does not teach are thinned tissue, a graft that is less than 0.45 mm thick and use of an expandable stent with a relatively impervious graft.

The three features of claim 1 that Love does not teach are interrelated. One skilled in the art would understand the importance of using an expandable stent for deploying a relatively impervious graft. It is clear that a graft that is as thin as possible is preferred. Yet it is clear from Love that even natural tissue wrapped about a stent is often not strong enough for use even with a non-expandable stent and must be strengthened. Thus a person skilled in the art would not countenance thinning a candidate tissue as this would necessarily weaken the tissue, something that would, as is understood from Love make such a tissue too weak for use even with a non-expandable stent. Further a person skilled in the art would not countenance deploying a relatively impermeable graft, especially not one weakened by thinning, with an expandable stent, as during expansion of the expandable stent the graft is subjected to severe mechanical stress and understood from Love is that even thick tissue are barely durable enough for use in a non-expanding stent. One skilled in the art would seek methods of strengthening existing full-thickness tissues as suggested by Love (p.9 ll.9-17) and consider grafts thinner than 0.45 mm as an unattainable Holy Grail.

The Examiner posits that one of average skill in the art would find guidance in Winston *et al.* to overcome the shortcomings of the teachings of Love. Applicant respectfully traverses this position.

One skilled in the art attempting to overcome the shortcomings of Love would dismiss the applicability of Winston *et al.* despite the fact that Winston *et al.* teach a graft deployed

on an expandable stent: Winston *et al.* teach a mechanically weak, porous and permeable graft that is effective for implementing the teachings of Winston *et al.* even if torn or otherwise damaged during the stent expansion process. One skilled in the art would correctly assume that the thinning process of Winston *et al.* weakens and possibly perforates the tissue to some extent, something that is advantageous when implementing the teachings of Winston *et al.* but defeats the desired relative imperviousness of Love and of the present invention.

Further, Winston *et al.* teach that a thinned layer of tissue is made expandable by meshing (c.3 ll.54-57), a process that perforates the tissue. Thus, rather than providing one skilled in the art with a direction as to how to obtain a relatively impervious graft that is sufficiently strong and expandable by thinning tissue to use with a non-expandable stent of Love or with an expandable stent, Winston *et al.* teaches one skilled in the art how to obtain a porous, permeable, expandable graft by thinning and meshing of tissue.

In conclusion, Applicant believes that claim 1, as well as claims 2-9, 35-37, 43-45 and 47-49 dependent therefrom, describe novel subject matter that is not-obvious from the cited art alone or in combination, and is therefore in condition for allowance.

Re claim 36: 35 U.S.C. 103(a) Rejection – WO 97/24081 (Love) in view of 6,117,166 (Winston *et al.*)

Claim 36 adds a limitation that the graft is longer than said stent by not more than 5% to the stent assembly of claim 1. The Examiner posits that such a limitation is *prima fascia* obvious. Applicant respectfully traverses this position.

In any case, since claim 36 depends from claim 1, and claim 1 is in condition for allowance, claim 36 is also in condition for allowance.

Re claim 5: 35 U.S.C. 103(a) Rejection –6,117,166 (Winston *et al.*) in view of WO 94/15583 (Narciso)

Claim 5 adds a limitation that the stent assembly of claim 1 includes at least one therapeutic or diagnostic agent releasably contained in the cylindrical jacket.

As discussed above, Winston *et al.* provide a device to simultaneously preserve patency and to resurface the internal walls of damaged blood vessels by re-growing a healthy endothelial layer on damaged inner surface of a blood vessel by bringing endothelial cells in proximity to the inner surface. The endothelial cells migrate to and grow over the damaged inner surface. An explicitly stated advantage of the device of Winston *et al.* is that such a graft avoids the use of pharmaceutical agents (c.2 ll. 28-30).

Narciso teaches a stent that is at least partially bioabsorbable comprising at least one medicament.

The Examiner posits that it would have been obvious to combine the teachings of Narciso with those of Winston *et al.* and thus provide a stent assembly of claim 5. Applicant respectfully traverses this position. One skilled in the art would not be motivated to combine the teachings of Winston *et al.* with those of Narciso as Winston *et al.* explicitly obviates such a combination.

In any case, since claim 5 depends from claim 1, and claim 1 is in condition for allowance, claim 5 is also in condition for allowance.

Re claim 35: 35 U.S.C. 103(a) Rejection – WO 97/24081 (Love) in view of 6,117,166 (Winston *et al.*) and in view of 5,653,747 (Dereume)

Claim 35 adds a limitation that the cylindrical jacket of the stent assembly of claim 1 is substantially shorter than the stent.

As discussed above, Love teaches a jacketed stent having a thick and relatively impervious tissue jacket wrapped around a non-expandable stent.

As discussed above, Winston *et al.* provide a device to simultaneously preserve patency and to resurface the internal walls of damaged blood vessels by re-growing a healthy endothelial layer on damaged inner surface of a blood vessel by bringing endothelial cells in proximity to the inner surface. The endothelial cells migrate to and grow over the damaged inner surface.

Dereume teaches an expandable stent having an expandable porous jacket of biocompatible fibers. The jacket provides a matrix on which and through which normal (as opposed to unorganized) cell growth occurs. In Figure 2 of Dereume is depicted that stent extends substantially the full length of the jacket where there are small protrusions of the end zone of the stent that can serve as anchoring fixation members (c.5 ll.19-23).

The Examiner posits that it would have been obvious to combine the teachings of Dereume with those of Love and Winston *et al.* and thus provide a stent assembly of claim 35. Applicant respectfully traverses this position.

One skilled in the art would have no motivation to combine three such disparate teachings. Love teaches a relatively impervious graft. Winston *et al.* teach a graft that resurfaces a scarred vessel by disintegrating. Dereume teaches a permeable synthetic jacket serving as a matrix to allow normal cell growth. There is no unifying concept in these teachings to motivate one of ordinary skill in the art to combine any two, much less all three of the teachings.

It is important to note that explicitly stated in claim 1 of Dereume is that the stent extends substantially the full length of the jacket and is not "substantially shorter" as required in claim 35. Thus, even if one were motivated to combine the teachings of Love, Winston *et*

al. and Dereume, such a combination does not include the limitation of a graft that is substantially shorter than supporting stent nor does such a combination render the limitation obvious.

In any case, since claim 35 depends from claim 1, and claim 1 is in condition for allowance, claim 35 is also in condition for allowance.

Independent claim 29 and claims 30, 38, 41 and 42 dependent therefrom now feature language that is entirely supported by the specification. Further, the Examiner has not rejected any of claims 29, 30, 38, 41 and 42 based upon prior art. Applicant is of the opinion that claims 29 and 30, 38, 41 and 42 dependent therefrom are in condition for allowance.

Independent claim 1 and claims 2-9, 35-37, 43-45 and 47-49 dependent thereform now feature that is entirely supported by the specification and that is neither anticipated by nor obvious in light of the prior art, alone or in combination. Applicant is of the opinion that claims 1 and 2-9, 35-37, 43-45 and 47-49 dependent therefrom are in condition for allowance.

Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully Submitted,

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